UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

This document relates to:

The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.
Case No. 18-op-45090

The County of Cuyahoga, et al. v. Purdue Pharma L.P., et al.
Case No. 17-op-45004

MDL No. 2804

Hon. Dan Aaron Polster

DEFENDANTS' OPPOSITION TO TRACK ONE PLAINTIFFS' MOTION FOR PARTIAL SUMMARY ADJUDICATION OF DEFENDANTS' DUTIES UNDER THE CONTROLLED SUBSTANCES ACT [DEFS' CSA "DUTIES" BRIEF]

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I. INTRODUCTION

Plaintiffs have moved for a ruling on the scope of the federal Controlled Substances Act ("CSA") so that this Court can determine "whether any of the Defendants are in compliance." *See* Dkt. 1887-1 at 1. Plaintiffs assert that "Defendants' compliance with the CSA is relevant, including [for] claims" under federal and state RICO laws and public nuisance law. *Id.* Those contentions confirm that various of Plaintiffs' claims should be dismissed as preempted by federal law because they would interfere with and frustrate the purpose of the federal CSA registration framework, among other reasons, and/or for lack of a cause of action for the reasons set forth in other motions.[1]

On the merits, Plaintiffs' motion is fatally flawed because it misreads the CSA and its regulations. Plaintiffs are wrong about what the CSA and its regulations require. Plaintiffs attempt to create legal "duties" under the CSA and its regulations that trigger automatic legal liability that can be transformed into a basis for state law liability. Dkt. 1887-1 at 3-5; s*ee* Dkt. 1910-1 at 20–25 (arguing purported failure to comply with the CSA and regulatory provisions establishes nuisance *per se*, serves as a predicate act under RICO, and establishes a standard of care for their negligence claims). But the CSA's provision regarding registrants' "maintenance of effective controls against diversion" does not create that sort of legal "duty." Rather, that effective controls provision is one of several factors enumerated in the statute that DEA is to consider (under authority delegated by the Attorney General, 21 U.S.C. § 871; 28 C.F.R. § 0.100(b)) when DEA

[1] *See, e.g.*, Defendants' Memorandum in Response to Plaintiffs' Motion for Partial Summary Adjudication That Defendants Did Not Comply with Their Duties under the Federal Controlled Substances Act to Report Suspicious Opioid Orders and Not Ship Them ("Defs' CSA 'Compliance' Br."), filed contemporaneously herewith, at Argument I; Dkt. 1883-1; Dkt. 1926-1; Dkt. 1873-1 at 5–17; Dkt. 491-1 at 35–38.

determines whether it would be "consistent with the public interest" to issue, suspend, or revoke a federal registration. 21 U.S.C. § 823(a), (b), (d), (e).

Nor do DEA regulations stating that registrants "provide effective controls and procedures to guard against theft and diversion of controlled substances" create the "duties" that Plaintiffs propose trigger automatic liability. 21 C.F.R. § 1301.71(a). Rather, the regulations specify that, to determine whether a registrant has provided effective controls, DEA is to use a set of security requirement regulations, including a suspicious order regulation, *id*., and that "[s]ubstantial compliance" with those regulations "may be deemed sufficient" by "the Administrator after evaluation of the overall security system and needs of the applicant or registrant." 21 C.F.R. § 1301.71(b). The regulations' sole reference to "suspicious orders" provides only for registrants to identify and inform DEA of suspicious orders—defined as orders of "unusual size," "unusual frequency," or "deviating substantially from a normal pattern." 21 C.F.R. § 1301.74(b). It does not include a requirement that no such orders be shipped.

In addition, Plaintiffs ignore that there is no duty owed *to them* under the CSA or its regulations. This Court has held that the CSA and its regulations were "not intended" to protect public entities like Plaintiffs from such alleged harms. Dkt. 1680 at 24–25.

The limited scope of the CSA and its regulations is not—and legally cannot be—expanded by two DEA "Dear Registrant" letters or the two revocations of non-party companies' registrations (*Southwood* and *Masters*) that Plaintiffs cite. The letters do not have the force or effect of law because they are, at most, interpretive materials, not notice-and-comment rules. Also, the letters' vague, shifting articulations of different policies and priorities are of no persuasive effect or deferential weight under any standard. Indeed, DEA has unequivocally stated that the letters were *not* intended to have binding effect on registrants. And the registration revocations cited by

Plaintiffs address situations of individual companies involving case-specific matters that do not bind other registrants, including any of the Defendants.

Plaintiffs ask the Court to graft onto the CSA and its regulations legal "duties" that trigger automatic legal liability, but they do not exist. In particular, these provisions do not require, as Plaintiffs contend, that registrants "not ship[] suspicious orders of prescription opioids unless and until they have determined that diversion is not likely." Dkt. 1887-1 at 1. Even worse than that incorrect statement of federal law, Plaintiffs suggest that various purported "duties" are undisputed. To the contrary, testimony of current and former DEA employees is in conflict as to the agency's views, and while such testimony may support a claim that Defendants justifiably relied on assurances from DEA that their conduct was compliant, it cannot be used to expand the law beyond its appropriate scope.[2] Given the plain meaning and structure of the CSA and its regulations, the Court should deny the motion, and reject Plaintiffs' request for declaration of the various "duties" they propose.

[2] Plaintiffs attach to their motion a deposition statement they quote of DEA's Rule 30(b)(6) witness (Dkt. 1887-1 at 5; Dkt. 1887-3) (Prevoznik Tr. (Apr. 18, 2019) at 771:7–20), implying that his view of the law can expand the statute and regulations beyond their plain meaning. But the scope of the CSA and its regulations is a question of law for the Court; DEA testimony cannot create additional requirements. *See Chavez v. Carranza*, 559 F.3d 486, 498 (6th Cir. 2009); *Molecular Tech. Corp. v. Valentine*, 925 F.2d 910, 919 (6th Cir. 1991). Moreover, the same witness elsewhere contradicted that incorrect view of federal law. Prevoznik Tr. (Apr. 17, 2019) at 167:5–12 (Dkt. 1969-12/1983-9).

In any event, summary adjudication cannot be entered here because the Prevoznik testimony is disputed by other witnesses as well. *See* Rannazzisi Tr. (May 15, 2019) at 534:19–21 (Dkt. 1969-21/1983-18); Ashley Tr. (Mar. 15, 2019) at 242:12–19, 251:17–21 (Dkt. 1956-7/1974-7); Rafalski Tr. (May 13, 2019) at 134:25–135:7, 349:22–350:8 (Dkt. 1969-18/1983-15); Ex. 1, Michael Mapes Tr. (July 11, 2019) at 91:8–12 ("Q. Does the regulation [21 C.F.R. § 1301.74(b)] say anything about whether a registrant can ship a suspicious order? . . . A. No, it doesn't."); Ex. 1, Mapes Tr. (July 12, 2019) at 535:11–24. And witnesses have acknowledged that DEA has taken inconsistent positions over the years about the scope of the CSA and its regulations. *See* Defs' CSA Compliance Br., Background G, H; *id.* at Argument II.

II. ARGUMENT

Plaintiffs contend that the Court needs to adjudicate the meaning of the federal CSA and its regulations, and Defendants' compliance with the statute and regulations, as critical components of their case. That contention reinforces the fact that the Court should dismiss the case because federal law preempts claims that interfere with or frustrate the purposes of the federal registration scheme. The Court should enter judgment for Defendants on these grounds and because Plaintiffs lack a cause of action to enforce the CSA. *See* p. 1, n.1, above.

To the extent the Court nonetheless finds the CSA or its regulations somehow pertinent to Plaintiffs' surviving claims, Plaintiffs' motion for a ruling that the CSA and its regulations create legal "duties" that support Plaintiffs' claims is fatally flawed as a matter of law. Plaintiffs seek to establish what they term legal "duties" in order to argue that Defendants "violated" such "duties" in a manner that establishes predicate acts and a pattern of racketeering for purposes of RICO, Dkt. 1910-1 at 20–23, and that constitutes a "violation" of a controlled substances law for purposes of their public nuisance and negligence claims, *id*. at 23–25.

But Plaintiffs' proposed view of federal law is incorrect. The provisions of the CSA and its regulations cited by Plaintiffs—regarding effective controls against diversion and suspicious orders—form part of a series of factors for DEA to consider in determining whether to issue, suspend, or revoke a registration. The text and structure of the CSA and its regulations clearly set out this federal registration framework, and Plaintiffs cannot transform that framework into the felonious and automatic legal liability they propose.

A. The Effective-Controls Provisions of the CSA Do Not Create the Legal "Duties" Posited by Plaintiffs.

Plaintiffs argue that the CSA's provisions on "maintain[ing] effective controls against diversion" imposes various legal "duties" on Defendants that support their claims. Dkt. 1887-1

at 1, 3. They then argue that Defendants violated that "duty" so as to render their manufacture and distribution of opioids a felony. Dkt. 1910-1 at 22. But the statute's effective-controls provisions do not create such a legal "duty" as Plaintiffs assert, much less any such duty *to Plaintiffs*. Rather they are part of a federal registration process.

The CSA requires registration for certain manufacturers, distributors, pharmacies, and others. Congress directed that DEA (as delegatee of the Attorney General, 21 U.S.C. § 871; 28 C.F.R. § 0.100(b)) "shall register an applicant" unless it determines "that the issuance of such registration is inconsistent with the public interest." 21 U.S.C. § 823(b). Congress further provided that in determining whether to suspend or revoke such registrations, DEA is to determine whether registration is consistent "with the public interest." *See* 21 U.S.C. § 823(b); 21 U.S.C. § 823(e) (similar for schedule III, IV, and V); *see also* 21 U.S.C. § 823(a) (similar for manufacturers and schedule I or II); 21 U.S.C. § 823(d) (similar for schedule III, IV, and V); *cf.* 21 U.S.C. § 824(a)(4) (referencing same considerations for suspension or revocations of registration).

Congress specified that, "[i]n determining the public interest" for these registration purposes, DEA is to consider several factors, including "maintenance of effective controls against diversion" of controlled substances into other than legitimate channels; compliance with state and local law; promotion of technical advances in manufacturing these substances; prior conviction record; past experience in the manufacture or distribution of controlled substances; and other factors consistent with public health and safety. 21 U.S.C. § 823(a)(2)–(6), (b)(2)–(5), (d)(2)–(6), (e)(2)–(5).

Thus, Congress created a registration process in which several factors, including maintenance of effective controls against diversion, are relevant considerations for the federal

agency charged with enforcing the statute, when determining whether an applicant's registration is consistent with the public interest. Even then, Congress specified that to permanently suspend or revoke registration, an individualized proceeding before the federal agency is required, including an order to show cause, a hearing, opportunity "to submit a corrective action plan on or before the date of appearance," and judicial review. 21 U.S.C. § 824(c).

That federal registration framework does not impose a legal "duty," the violation of which would trigger the automatic legal liability Plaintiffs posit. Rather, Congress specified that federal registration is to address multiple considerations, including guarding against diversion of controlled substances while recognizing that "[m]any of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." 21 U.S.C. §§ 801(1), 801(2). That registration authority lies solely with the federal government.

Plaintiffs attempt to extrapolate from the CSA's effective-controls provision three specific "duties"—"identification," "reporting," and "no-shipping," regarding suspicious orders. Dkt. 1887-1 at 4. Plaintiffs' suggestion that those purported "duties" are established by the CSA is without support. To begin with, Congress did not use the term "suspicious order" when it enacted the CSA in 1970. And the text of the CSA contained no requirement for registrants regarding such orders at the relevant time. The Court "must presume that [the] legislature says in a statute what it means and means in a statute what it says there." *Dodd v. United States*, 545 U.S. 353, 357 (2005) (quoting *Conn. Nat. Bank v. Germain*, 503 U.S. 249, 253 (1992)); *see also Jama v. Immigration & Customs Enf't*, 543 U.S. 335, 341 (2005) ("[w]e do not lightly assume that Congress has omitted from its adopted text requirements that it nonetheless intends it apply").

Plaintiffs alternatively seek to anchor those three purported "duties" in the CSA regulations, in their effort to trigger automatic legal liability, Dkt. 1887-1 at 4–9, but that effort is belied by the text and structure of those very regulations as set forth below in Part II.B. Also, the agency statements on which Plaintiffs attempt to rely have no controlling legal effect. In addition, they are imprecise and ever-changing, not rooted in the statute or regulations, and contrary to earlier longstanding agency views, as demonstrated in Part II.D.

B. The CSA Regulations Regarding Effective Controls Do Not Create the Legal "Duties" Posited by Plaintiffs, and Specifically Do Not Include Plaintiffs' Purported No-Shipping Requirement.

The regulations cited by Petitioners do not create the legal "duties," in the manner Plaintiffs assert. The text and structure of the regulations demonstrate that they govern the federal registration process and the consequence of a purported "violation" does not trigger automatic legal liability for purposes of RICO, public nuisance, or negligence claims, as Plaintiffs would have the Court believe. Dkt. 1887-1 at 1; Dkt. 1910-1 at 20–25.

The regulations on which Plaintiffs rely echo the text of the statute, stating that federal registrants "shall provide effective controls and procedures to guard against theft and diversion of controlled substances," 21 C.F.R. § 1301.71(a). The next sentence of the regulation specifies precisely what "effective controls" means: "In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72–1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion." 21 C.F.R. § 1301.71(a). And the regulations explicitly provide that "[s]ubstantial compliance with the standards set forth in §§ 1301.72–1301.76 may be deemed sufficient" by the agency "after evaluation of the overall security system." 21 C.F.R. § 1301.71(b).

Those regulations at §§ 1301.72–1301.76—which establish what constitutes "effective controls"—largely address the physical handling of controlled substances. They detail requirements for storage areas, cabinets, vaults, cages, alarms, compounding areas, and the like at times when controlled substances are under the registrant's direct control, such as in their own facilities. *See, e.g.*, 21 C.F.R. § 1301.72. Those regulations also include a provision for identifying and informing DEA about "suspicious orders," defined as orders of "unusual size," "unusual frequency," or "deviating substantially from a normal pattern." 21 C.F.R. § 1301.74(b).

That regulatory text and structure demonstrate that the provisions for identifying and informing DEA of suspicious orders do not impose any legal "duty" on registrants owed to Plaintiffs, much less one that if violated would trigger automatic legal liability or constitute a felony. Rather, those regulations, including the suspicious order regulation, are factors considered by DEA in determining whether to deem "substantial compliance" sufficient for purposes of effective diversion controls. They are part of an assessment of the "overall security system" of a registrant. 21 C.F.R. § 1301.71(b). And that assessment, in turn, is part of the regulatory framework governing federal registrations. 21 C.F.R. § 1301.01 *et seq*. Even the revocation of a registration is not punitive, but rather a remedial measure. *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,503–36,504 (DEA July 3, 2007).

Furthermore, Plaintiffs are doubly wrong in their argument that the Court should rule "as a matter of law" that registrants are required to "stop suspicious orders, pending investigation." Dkt. 1887-1 at 1. There is no such provision anywhere in the regulations that includes a requirement not to ship suspicious orders.

The suspicious order regulation, 21 C.F.R. § 1301.74(b), details the actions that registrants are to take regarding suspicious orders. Section 1301.74(b) contains three sentences and only three sentences:

- "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances."
- "The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant."
- "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

21 C.F.R. § 1301.74(b).

Nothing in the regulation provides that suspicious orders not be shipped. Indeed, the regulation does not indicate that suspicious orders necessarily have a likelihood of being diverted, despite Plaintiffs' misleading use of that terminology. *See* Dkt. 1887-1 at 7 (suggesting that, "by definition," suspicious orders "bear some indicia of diversion").

Expanding the regulations to impose a requirement not to ship suspicious orders would be contrary to the regulation, in light of the details that the regulations provide. If the regulations were intended to create a requirement that suspicious orders not be shipped, that detailed regulatory text surely would have included such a provision, for when DEA has determined that other limitations on distribution are warranted by the CSA, DEA has so provided in the regulations explicitly through notice-and-comment rulemaking. For example, § 1301.74(d) includes a prohibition against shipping controlled substances in a limited situation, specifying that a registrant "*shall not distribute* any controlled substance listed in Schedules II through V as a complimentary sample to any potential or current customer [unless certain conditions are satisfied]." 21 C.F.R. § 1301.74(d). Further, § 1301.74(e) specifies when a registrant has other responsibilities regarding shipping: "When shipping controlled substances, a registrant is responsible for selecting common

or contract carriers which provide adequate security to guard against in-transit losses." 21 C.F.R. § 1301.74(e). Finally, § 1301.74(f) addresses responsibility for certain agents of registrants: "When distributing controlled substances through agents (e.g., detailmen), a registrant is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents." 21 C.F.R. § 1301.74(f).

Plaintiffs are similarly incorrect in their argument that shipment of suspicious orders is contingent on an investigation of the customer that establishes that diversion is not likely, Dkt. 1887-1 at 1–9. There is no support for Plaintiffs' theory that federal law requires Defendants to take on responsibilities to investigate other registrants, akin to DEA's responsibilities. Rather, the regulations are specific as to the responsibility of registrants regarding customers. Section 1301.74(a) states that, "[b]efore distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry" with the federal or state registration agency to determine if the person is so registered. 21 C.F.R. § 1301.74(a). That regulation makes clear that a distributor is to make a good faith inquiry that the recipient is *registered*. But it is DEA—not other registrants—that is charged with ensuring that registrants are acting in compliance with law.

Again, the regulations speak to the point at issue and are more narrow than what Plaintiffs claim. If there were an intent to create a requirement for registrants to investigate customers before shipping orders, that regulatory text surely would have included such a provision.

DEA acted consistently with the plain meaning of the effective-controls regulations from their promulgation in 1971 for more than 35 years thereafter. Testimony from retired DEA witnesses with personal knowledge of DEA's oversight of registrants confirmed that the standard industry practice for at least thirty years had been to inform DEA of suspicious orders after they

had been shipped. Ex. 1, Mapes Tr. 92:1–12; Wright Tr. 72:4–10; 115:17–116:12 (Dkt. 1972-12/1985-24). Both Mapes and Wright testified that DEA "blessed" the practice and viewed it "as compliant with the regulation for suspicious orders." Wright Tr. 72:12–16 (Dkt. 1972-12/1985-24); Ex. 1, Mapes Tr. 520:14–521:18. And both Mapes and Wright testified that the views expressed by certain DEA officials in 2007 were a substantial change in view on whether a registrant could ship an order that it had informed DEA was a suspicious order. Wright Tr. 110:8–19 (Dkt. 1972-12/1985-24); Ex. 1, Mapes Tr. 125:3–22.

Nothing in the statute or regulations requires, as Plaintiffs propose, each registrant to "police" the entire supply chain, including interactions between physicians, pharmacies, patients, and other persons that are beyond their control. Contrary to what Plaintiffs say, the regulations do not impose, let alone even suggest, a duty on registrants to launch investigations of customers to examine their business operations, perform audit-like examinations of their customers' internal financial records, inspect their premises, evaluate their procedures for dispensing by licensed pharmacists further down the supply chain, or to undertake other scrutiny before shipping orders. The absence of such duty makes sense because participants in other parts of the regulated supply chain are, themselves, registrants with DEA subject to its regulation. Indeed, other federal statutes such as patient privacy laws and the lack of *private* subpoena or warrant authority would in many situations pose obstacles to the approach Plaintiffs say is required.

The CSA, instead, vests the *federal government*, not private companies, with the authority to investigate suspicious orders. Congress granted the federal government law enforcement authority, investigative tools, and resources to enforce the federal regulatory framework through official agency regulations and actions, within the confines of the federal statute. That authority includes subpoena power, 21 U.S.C. § 876, specific search warrant authority, 21 U.S.C. § 879,

inspection authority, 21 U.S.C. § 880, forfeiture authority 21 U.S.C. § 881, and other powers, including broad access to detailed data from a wide range of businesses in all segments of the supply chain, and the resources of the federal government (resources that depend on government appropriations and allocation, not on commandeering private companies). The regulatory framework provides that registrants will inform federal authorities of suspicious orders for DEA to determine whether to take additional action. That does not mean that registrants are to conduct investigations at other companies—to the contrary, they inform DEA, which has law enforcement authority and investigative tools.

In sum, the effective control provisions focus on circumstances where controlled substances are being stored or handled by a registrant in its own segment of the supply chain. That is consistent with Congress's focus on avoiding the diversion of controlled substances from the highly regulated, closed distribution system into illegitimate channels.

According to Plaintiffs, however, there is some "further duty"—beyond what the statute and regulations provide—that requires registrants to "refrain from shipping suspicious orders until the registrant can determine, through investigation, that the order is not likely to be diverted." Dkt. 1887-1 at 2. The Court should reject that argument because there is no basis in the statute or regulations to conclude there is any such "further duty." Despite Plaintiffs' urging, this Court cannot create a requirement not to ship suspicious orders that is found nowhere in the CSA and its regulations. "The judiciary may not, in the face of such comprehensive legislative schemes, fashion new remedies that might upset carefully considered legislative programs." *Nw. Airlines, Inc. v. Transp. Workers Union of Am., AFL-CIO*, 451 U.S. 77, 97 (1981); *see also id.* ("The presumption that a remedy was deliberately omitted" is "strongest when Congress has enacted a

comprehensive legislative scheme including an integrated system of procedures for enforcement.").

On top of all this, Plaintiffs fail entirely to establish any CSA duty owed *to them*, or any county. This Court recently held that "none" of these statutes and regulations is intended to protect public entities like the Plaintiffs "from the harms they allege." Dkt. 1680 at 25; *see also id.* at 24 ("The CSA was not intended to protect sovereigns like the Tribes from spending more on addiction-related public services when rates of addiction increase.").

C. The 2018 Amendments to the CSA Confirm That the CSA Does Not Include a Requirement Not to Ship Suspicious Orders or Impose the Legal "Duties" Plaintiffs Propose.

Plaintiffs argue that Congress's amendment of the CSA in 2018 (through the SUPPORT for Patients and Communities Act) demonstrates that the CSA and its regulations have long required registrants not to ship suspicious orders. Dkt. 1887-1 at 7. To the contrary, those amendments further confirm that the CSA does not include a requirement not to ship suspicious orders or impose other legal "duties" triggering automatic legal liability as proposed by Plaintiffs.

In October 2018, Congress added to the CSA a provision regarding suspicious orders comparable to the regulations. *See* Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act ("SUPPORT for Patients and Communities Act"), Pub. L. No. 115-271, 132 Stat. 3894, 3956 (2018) (codified as 21 U.S.C. §§ 802(a)(1), (3), 832). Congress used a definition of "suspicious orders" that is substantially similar to the regulation, 21 U.S.C. § 802(57), and it provided for registrants to "design and operate a system to identify" such orders and to "notify" DEA of such orders. It did not include a prohibition against shipping such orders or requiring customer investigations (let alone one that could have retroactive effect). If, as Plaintiffs suggest, Congress intended to include such requirements, it would have done so when it amended the CSA.

Plaintiffs argue that a background note related to a different provision in the 2018 amendments regarding data somehow overrides Congress's failure to include in the suspicious order provision a requirement not to ship. Dkt. 1887-1 at 7–9. Plaintiffs contend that although "Congress did not amend the CSA to impose more explicitly the no-shipping requirement," it did not do so "because it understood that the duty *already* existed under the CSA." *Id.* at 8. But the Supreme Court rejects such efforts to imply congressional acquiescence by silence. The Court has explained that, "when, as here, Congress has not comprehensively revised a statutory scheme but has made only isolated amendments," then "[i]t is impossible to assert with any degree of assurance that congressional failure to act represents affirmative congressional approval of the [prior] interpretation.'" *Alexander v. Sandoval*, 532 U.S. 275, 292 (2001) (citation omitted). Moreover, a subsequent proposal in the current Congress to amend the CSA to prohibit shipping of suspicious orders, *see* H.R. 3878 (116th Cong., 1st Sess.), further demonstrates that Plaintiffs are wrong that any such requirement already exists. *See* McKinley, Dingell Introduce Bill to End Pill Dumping, Bring Accountability to Suspicious Order Shipments (July 23, 2019), *available at https://mckinley.house.gov/news/documentsingle.aspx?DocumentID=2611* (announcing introduction of Bill to require registrants "to not only report but halt suspicious orders," sponsor explaining that "[c]urrently, under the Controlled Substances Act drug manufacturers, and distributors are only required to report suspicious orders of opioids to the DEA. This legislation would require registrants to halt, investigate, and report suspicious orders of controlled substances.").

D. DEA's "Dear Registrant" Letters and Registration Revocations of Nonparties Do Not Support Plaintiffs' Motion.

The Court should reject Plaintiffs' effort to rewrite the CSA and its regulations based on letters written by a DEA official and the revocation of registrations for two non-party companies.

Neither the letters nor the revocations carry the force or effect of binding law against Defendants and cannot support Plaintiffs' request for a declaration of legal "duties."

1. "Dear Registrant" Letters Have No Binding Legal Effect.

The "Dear Registrant" letters that Plaintiffs cite were intended to express policy views and priorities of certain DEA officials as to how federal law should be enforced. Dkt. 1887-1 at 6–7 (citing letters by J. Rannazzisi). But letters like those "do not have the force and effect of law and are not accorded that weight in the adjudicatory process." *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 99 (1995). Letters and other documents that express an agency official's view of the law, but are not substantive rules promulgated through notice-and-comment rulemaking, merely "go to what the administrative officer *thinks* the statute or regulation means." *Dismas Charities, Inc. v. U.S. DOJ*, 401 F.3d 666, 679 (6th Cir. 2005) (emphasis added). Simply put, agencies cannot make law through sending out letters. *Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 643 (6th Cir. 2004).

Even DEA has acknowledged that these letters "were not intended to have binding effect," that they do not "bind the Agency," and "that [when] an official vested with prosecutorial authority issues a letter advising entities that he views certain conduct as violative of a regulation . . . [the letter] does not establish that those entities are foreclosed from challenging that interpretation in any subsequent proceeding." *Masters Pharm., Inc.*, 80 Fed. Reg. 55,418, 55,475 (DEA Sept. 15, 2015).

Plaintiffs are incorrect that the letters would be entitled to *Chevron* deference, Dkt. 1887-1 at 8–9. The letters are not notice-and-comment regulations and thus are not legislative rules. They are at most "interpretive," and the Supreme Court has made clear that such interpretations do not warrant judicial deference. "[T]he critical feature of interpretive rules is that they are issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers. The absence of a notice-and-comment obligation makes the process of issuing

interpretive rules comparatively easier for agencies than issuing legislative rules. But that convenience comes at a price: Interpretive rules do not have the force and effect of law and are not accorded that weight in the adjudicatory process." *Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1204 (2015) (quotation marks and citation omitted). Under controlling law, "[i]nterpretations such as those in opinion letters—like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law—do not warrant *Chevron*-style deference." *Christensen v. Harris County*, 529 U.S. 576, 587 (2000)); *Air Brake Sys.*, 357 F.3d at 642–43 (these materials "have no claim to deference of any sort"). Plaintiffs themselves describe the letters as "interpretive," Dkt. 1887-1 at 6, and the cases they cite make clear they are not binding. *See Tennessee Hosp. Ass'n v. Azar*, 908 F.3d 1029, 1042 (6th Cir. 2018) ("legislative rules have the 'force and effect of law,' and interpretive rules do not").

In any event, the "Dear Registrant" letters are wholly unpersuasive as to the meaning of the CSA and its regulations, and would be entitled to no deference under any standard. *See Kisor v. Wilkie*, 139 S. Ct. 2400 (2019); *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). The CSA and its regulations are unambiguous in not imposing a requirement not to ship suspicious orders. The letters were written more than thirty years after the CSA was enacted and the regulations promulgated. DEA recognized that the guidance in the letters constituted a significant change and that implementing the change would be "harder" and would happen only gradually. Wright Tr. (Feb. 28, 2019) at 123:2–16 (Dkt. 1972-12/1985-24); Ex. 1, Mapes Tr. (July 12, 2019) at 518:10–14. Former DEA employee Kyle Wright testified, "It was truly a -- a different way of looking at it. Everybody was hard and fast on the past. Going past that was a hard reach." Wright Tr. at 123:10–13 (Dkt. 1972-12/1985-24); *see* Defs' CSA Compliance Br., Background G, H; *id.* at Argument II.

Far from identifying any statutory or regulatory support for the proposed requirement that suspicious orders not be shipped unless investigations of customers are undertaken, the letters reflect a variety of different (and shifting) suggestions for registrants, including to avoid filling an order that "might" be diverted, is "likely to be" diverted, or where the registrant "knew, or should have known" that the orders "were being diverted." *See* Dkt. 1887-4 (Sept. 27, 2006 Letter by J. Rannazzisi); Dkt. 1887-5 (Dec. 27, 2007 Letter by J. Rannazzisi). The letters assert that failure to follow these suggestions means that a registrant "may" be failing to maintain effective controls against diversion," not that they necessarily are doing so. *Id*. Notably, those letters do not identify any statutory or regulatory text that indicates that would be so. The fact that the letters go beyond the text of the statute and regulations renders them especially unpersuasive. The 2006 letter, for example, quotes the regulatory provisions relating to suspicious orders, but does not acknowledge that those provisions relate only to identifying and informing DEA of such orders and say nothing about not shipping. The letter points to the provisions in the statute relating to "maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels," 21 U.S.C. § 823(b)(1), but fails to acknowledge that any failure on that point does not trigger automatic legal liability. The letter also fails to note the absence in the statute of any requirement not to ship suspicious orders. *See* Dkt. 1887-4 (Sept. 27, 2006 Letter by J. Rannazzisi).

Put simply, the "Dear Registrant" letters were not subject to the scrutiny of notice-and-comment rulemaking, do not accurately describe the requirements contained in the CSA and regulations, are part of a range of inconsistent, vague, and changing statements by agency officials over the years, are entitled to no deference, and have no legally binding force.

2. The *Southwood* and *Masters* Revocations Do Not Impose Requirements Beyond the Parties to Those Proceedings.

Nor do the *Southwood* and *Masters* registration revocations Plaintiffs cite support their effort to obtain a broad ruling that federal law imposes a legal "duty" that registrants not ship suspicious orders, much less that registrants all owe some federal law duty *to Plaintiffs*. Dkt. 1887-1 at 4–7. Indeed, Plaintiffs' argument fails as a matter of law.[3]

Southwood and *Masters* relate to the revocations of the registration of two nonparty companies, and such individual agency adjudications do not impose controlling legal requirements beyond those companies. The Supreme Court has explained that agency actions like those might formulate policy and provide a general guide to action the agency might be expected to take in a similar future matter, but that "is far from saying" what the law is, much less that the "commands, decisions, or policies announced in adjudication are 'rules' in the sense that they must, without more, be obeyed by the affected public." *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 766 (1969) (plurality opinion); *see Conference Grp., LLC v. FCC*, 720 F.3d 957, 965–66 (D.C. Cir. 2013) ("The nature of adjudication is that similarly situated non-parties may be affected by the policy or precedent applied, or even merely announced in dicta. [But these policy pronouncements] represent no more than an interpretative precedent for the Commission to apply.") (internal quotation and citation omitted).

[3] Earlier in this litigation, the Special Master referenced *Masters* in a discovery ruling and suggested an interpretation of it, but did so without the benefit of briefing. Distributors moved for withdrawal of that portion of the ruling because it was unnecessary to the discovery ruling at issue and because the parties had not been afforded the opportunity to brief the issues. Dkt. 1188. The Special Master entered an order acknowledging that "distributors are correct" that it was only a discovery ruling "and not a definitive pronouncement on their legal obligations." Dkt. 1189 at 4. Plaintiffs' effort to obtain a summary adjudication that imposes on registrants such purported legal "duties" fails as a matter of law for the reasons set forth above.

For its part, DEA has explained that, when a "rule [i]s announced in an adjudication" rather than in a notice-and-comment regulation, a regulated entity is, "of course, free to argue why the rule should not be applied" in any future administrative action. *See Masters Pharm.*, 80 Fed. Reg. at 55,476. That is especially true where, as here, DEA has engaged with various other companies directly, reviewing registrations on a regular basis, 21 C.F.R. § 1301.13(e)(1), and has indicated its approval of various procedures of registrants through more specific dialogues about systems designed to maintain effective controls against diversion. *See, e.g.*, Ex. 2, DEA to Zimmerman (ABDCMDL00315783 at -5783); Ex. 1, Mapes Tr. (July 11, 2019) at 97:19–99:18, 101:18–103:5 (describing separate approval by DEA of ABDC program). Those interactions between companies and the regulator also do not mean that all actions that a company takes are required by federal law, but rather include actions to resolve disagreements without agreeing that federal law requires that result. The fact that Defendants may have made substantial efforts to comply with the views of a regulator adds nothing to the non-binding legal status of those views. *See Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 452 F.3d 798, 811 (D.C. Cir. 2006) ("[That] the agency's guidelines have been voluntarily followed by automakers and have become a de facto industry standard . . . does not demonstrate that the guidelines have had legal consequences.").

In any event, the registration revocations do not purport to impose the legal mandate for all registrants that Plaintiffs suggest, namely "not to ship suspicious orders until they have been cleared through investigation." Dkt. 1887-1 at 5. To the contrary, the revocations are case-specific adjudications that turn on the facts of the specific company's customers, shipping practices, prior history with DEA, and other circumstances. Also, the revocations are actions by an agency pursuant to its enforcement authority, not efforts at private causes of action for damages.

For example, in *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487 (DEA July 3, 2007), DEA faulted a distributor for supplying controlled substances to Internet pharmacies, entities DEA defined for purposes of that decision as pharmacies that filled prescriptions issued by physicians without a legitimate doctor-patient relationship, and thus were unlawful prescriptions. *Id.* at 36,488 n.2. DEA specifically declined to impose a requirement not to ship suspicious orders, noting that it had advised the company that DEA "cannot tell a distributor whether a particular order is legitimate or not" and "whether to ship was 'a business decision.'" *Id.* at 36,493. Then, based on a detailed analysis of the specific circumstances of that company in that case, DEA determined that certain of the statutory factors (maintenance of effective controls against diversion, past distribution experience, and public health and safety) supported the conclusion that continued registration of the company was "inconsistent with the public interest." *Id.* at 36,502–36,504 (citing 21 U.S.C. § 823(d)).

In *Masters*, DEA's revocation followed an earlier settlement between the company and DEA, which had resulted in a Memorandum of Agreement pursuant to which the company agreed to take certain action. The agency's subsequent revocation of that company's registration was based on an exhaustive review of the history and circumstances of the particular company and its conduct. Judicial review of DEA's revocation on that record in *Masters Pharmaceutical, Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017), did not, contrary to Plaintiffs' assertions, establish a "no-shipping duty." Dkt. 1887-1 at 4–5. The D.C. Circuit denied the petition for review, noting that the agency had relied on the company's violation of the regulation regarding informing DEA of suspicious orders, and declined to review the agency's interpretation of any shipping requirement because that interpretation had no effect on the agency's decision and provided no basis for the relief requested by the company. *Masters*, 861 F.3d at 222. The court expressly stated: "[E]ven

if the Administrator" had "impermissibly amended" the regulations to add a requirement not to ship suspicious orders as the company asserted, "that reading had no effect on his ultimate decision, and so provides no basis for relief." *Id*. at 221–222. Thus, the D.C. Circuit opinion provides no legal support for Plaintiffs' assertion that the CSA and its regulations impose a requirement not to ship suspicious orders.

III. CONCLUSION

For the reasons set forth above, the Court should deny Plaintiffs' Motion for Partial Summary Adjudication of Defendants' Duties Under the Controlled Substances Act, and should rule that the CSA and its regulations contain no requirement not to ship suspicious orders, nor do they impose the purported legal "duties" suggested by Plaintiffs to support their claims.

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Respectfully Submitted,

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[4] On June 10, 2019, Insys Therapeutics, Inc. and its affiliates each filed a voluntary case under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware, which are being jointly administered under Case No. 19-11292 (KG). In light of this bankruptcy proceeding, Insys does not join any of the summary judgment briefing filed in the MDL Track One cases.

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Teva Pharmaceutical Industries Ltd., Allergan plc f/k/a Actavis plc, and Mallinckrodt plc are respectively an Israeli corporation, Irish holding company, and Irish company that are not subject to and contest personal jurisdiction for the reasons explained in their pending motions to dismiss for lack of personal jurisdiction; they are specially appearing to join this Opposition as a result of the Court's deadline to file oppositions to dispositive motions, and, thus, they do not waive and expressly preserve their pending personal jurisdiction challenges.

In the Complaints, Plaintiffs lump Noramco together with Johnson & Johnson and its other affiliated entities, all Marketing Defendants, or all Defendants collectively. For this reason, Noramco joins this opposition even though it never manufactured, packaged, branded, marketed, promoted, distributed or sold the finished drug products that are at issue in this litigation. Indeed, there is no evidence that Noramco engaged in any wrongful conduct that might give rise to liability (*see* Noramco's Mem. ISO Mot. for J. on the Pleadings or, in the Alternative, S.J. (Dkt. 1902-1)), let alone that it had the duties Plaintiffs allege under the CSA or that it breached those alleged duties.

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